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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/701,536	06/18/2001	Gwong-Jen J. Chang	14114.0332U2	5492

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EXAMINER	
PARKIN, JEFFREY S	

ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 05/06/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/701,536	CHANG, GWONG-JEN J.	
	Examiner	Art Unit	
	Jeffrey S. Parkin, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *03* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *35-86* is/are pending in the application.

4a) Of the above claim(s) *55-68 and 70-86* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *35-54 and 69* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Detailed Office Action

Status of the Claims

Applicant's election with traverse of Group I (claims 35-54 and 69) in the communication dated 23 January, 2004, is acknowledged. The traversal is based upon the argument that a special technical feature is present in all the claims. This argument is clearly not persuasive. As set forth in the rejection below, prior art has been identified that renders the claimed invention *prima facie* obvious. Moreover, the claims are directed toward sundry products (e.g., nucleic acids, cells, polypeptides, viral particles) and methods (e.g., methods of immunization, methods of detection) that display disparate chemical structures and assay methodologies. Accordingly, a special technical feature is clearly absent from the claimed inventions. Accordingly, **the requirement is still deemed to be proper and is therefore made FINAL.** Claims 55-68 and 70-86 are withdrawn from further consideration by the examiner, pursuant to 37 C.F.R. § 1.142(b), as being drawn to a non-elected invention. Claims 35-54 and 69 are currently under examination.

37 C.F.R. §§ 1.821-1.825

This application clearly fails to comply with the requirements of 37 C.F.R. §§ 1.821-1.825. Applicants' attention is directed to the final rulemaking notice published at 55 F.R. 18230 (01 May, 1990) and 1114 O.G. 29 (15 May, 1990). If the effective filing date is on or after 01 July, 1998, see the final rulemaking notice published at 63 F.R. 29620 (01 June, 1998) and 1211 O.G. 82 (23 June, 1998). If the effective filing date is on or after 08 September, 2000, see the final rulemaking notice published in the Federal Register at 65 F.R. 54604 (08 September, 2000) and 1238 O.G. 145 (19 September, 2000). Applicants must provide an initial computer readable form (CRF) copy of the "Sequence Listing", an initial paper copy or compact disk

copy of the "Sequence Listing", as well as, an amendment directing its entry into the application. Applicant must also provide a statement that the content of the sequence listing information recorded in the computer readable form is identical to the written (on paper or compact disc) sequence listing and, where applicable, includes no new matter as required by 37 C.F.R. §§ 1.821(e), 1.821(f), 1.821(g), 1.825(b), and 1.825(d). If applicant desires the sequence listing in the instant application to be identical with that of another application on file in the United States Patent and Trademark Office, such request in accordance with 37 C.F.R. § 1.821(e) may be submitted in lieu of a new CRF.

Applicants are reminded that sequences appearing in the specification and/or **drawings** (e.g., Figures 2, 3, 6, and 7) must be identified by a sequence identifier (SEQ ID NO.:) in accordance with 37 C.F.R. § 1.821(d). Sequence identifiers for sequences appearing in the drawings may appear in the Brief Description of the Drawings. Applicant must provide appropriate amendments to the specification and/or drawings inserting the required sequence identifiers. Extensive amendments may necessitate the submission of a substitute specification.

Information Disclosure Statement

The information disclosure statements filed 05 March and 15 October, 2001, 01 March, 2002, 21 April and 23 July, 2003, and 13 February, 2004, have been placed in the application file and the information referred to therein has been considered.

35 U.S.C. § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(e) the invention was described in —

(1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effect under this subsection of a national application published under section 122(b) only if the international application designating the United States was published under Article 21(2)(a) of such treaty in the English language; or
(2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that a patent shall not be deemed filed in the United States for the purposes of this subsection based on the filing of an international application filed under the treaty defined in section 351(a).

Claims 35, 37-43, 45, 46, and 49-54 are rejected under 35 U.S.C. § 102(e) as being anticipated by Schmaljohn (2001). Schmaljohn provides isolated nucleic acids, and cells comprising said nucleic acids, containing transcriptional units encoding flaviviral antigens (e.g., CEE and RSSE prM/E). Since these units comprise the full-length prM gene, the prM signal sequence was also included. Moreover, the ATG start site was modified to include a Kozak concensus sequence. The transcriptional unit also included the CMV-IE promoter/enhancer region and a poly(A) terminator sequence.

35 U.S.C. § 103(a)

The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the

invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claim 69 is rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmaljohn (2001). The claim stipulates that the Kozak concensus sequence extends from -9 to +4 in the transcriptional unit. This teaching discloses that nucleotides were modified around the translation initiation codon to generate Kozak sequences as previously described (Kozak, M., 1989, *J. Cell. Biol.* 108:229). The precise location of these modifications with respect to the initiation codon was not disclosed. It would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to employ prepare a transcriptional unit with Kozak sequences as taught by Schmaljohn (2001). The precise location and number of modifications is simply a matter of routine experimentation, absent evidence to the contrary.

Claims 36, 44, 47, and 48 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Schmaljohn (2001) in view of Kochel *et al.* (2002). The teachings of Schmaljohn (2001) have been disclosed supra. This piece of art does not disclose YFV, DEN, JEV, or SLEV immunogens or compositions comprising the nucleic acid and a pharmaceutically acceptable carrier. Kochel and colleagues provide nucleic acid vaccines encoding the DEN prM/E proteins, as well as, compositions comprising the nucleic acids and a pharmaceutically acceptable carrier. Therefore, it would have been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to substitute the flaviviral RSSE/CEE prM/E coding regions provided by Schmaljohn (2001), with the flavivirus DEN prM/E coding regions disclosed by Kochel and colleagues, since this would allow the skilled artisan to express other flavivirus structural genes and to prepare multivalent vaccines. It would have also been *prima facie* obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition comprising nucleic acids encoding the flaviviral RSSE/CEE prM/E

coding regions, as provided by Schmaljohn (2001), with a pharmaceutically acceptable carrier, as provided by Kochel and colleagues, since this would facilitate the administration of these constructs to different hosts.

Non-statutory Double Patenting

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 U.S.P.Q. 644 (C.C.P.A. 1969); *In re Vogel*, 422 F.2d 438, 164 U.S.P.Q. 619 (C.C.P.A. 1970); *In re Van Ornum*, 686 F.2d 937, 214 U.S.P.Q. 761 (C.C.P.A. 1982); *In re Longi*, 759 F.2d 887, 225 U.S.P.Q. 645 (Fed. Cir. 1985); and *In re Goodman*, 29 U.S.P.Q.2d 2010 (Fed. Cir. 1993). A timely filed terminal disclaimer in compliance with 37 C.F.R. § 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 C.F.R. § 1.78(d). Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 C.F.R. § 3.73(b).

Claims 35-54 and 69 are **provisionally** rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10, 12-17, 28, 30, 32, 34, and 36 of copending Application No. 09/826,115 in view of Schmaljohn (2001). The claims of the instant application require a transcriptional unit encoding a prM signal sequence, Kozak concensus site, and flaviviral antigens. Schmaljohn (2001) provide prM signal sequences and Kozak concensus sequences. Therefore, it would have been *prima facie* obvious to one having ordinary skill in

the art at the time the invention was made to modify the claims of the '115 application to include a transcriptional unit with a prM signal sequence and Kozak sequences, as taught by Schmaljohn (2001), since this would facilitate the efficient expression of flaviviral antigens. This is a **provisional** obviousness-type double patenting rejection.

Correspondence

Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (571) 272-0908. The examiner can normally be reached Monday through Thursday from 9:30 AM to 7:00 PM. A message may be left on the examiner's voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, Laurie Scheiner or James Housel, can be reached at (571) 272-0910 or (571) 272-0902, respectively. Direct general inquiries to the Technology Center 1600 receptionist at (571) 272-1600.

Formal communications may be submitted through the official facsimile number which is (703) 872-9306. Hand-carried formal communications should be directed toward the customer window located in Crystal Plaza Two, 2011 South Clark Place, Arlington, VA. Applicants are directed toward the O.G. Notice for further guidance. 1280 O.G. 681. Informal communications may be submitted to the Examiner's RightFAX account at (571) 273-0908.

Respectfully,

Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

01 May, 2004